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By _____
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Jason G. Tebbutt (Reg. No. 55,671)
(Typed or printed name of person)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

IN RE APPLICATION OF: Nancy J. Harper, et. Al.

APPLICATION NO.: 10/771,985

FILING DATE: February 3, 2004

TITLE: Sertraline Oral Concentrate

Examiner: Oh, Taylor V.

Group Art Unit: 1625

Commissioner for Patents
PO Box 1450
Arlington, VA 22313-1450

Sir:

APPEAL BRIEF

STATEMENT OF THE CASE

This is an appeal in response to the Final Rejection of November 16, 2004, finally rejecting claims 1-13 in the above identified application, under 35 USC 103(a), as being unpatentable over Doogan et al. (U.S. 4,962,128) in view of Howard et al. (U.S. 5,597,826).

REAL PARTY IN INTEREST

The real party in interest in the present appeal is Pfizer Inc. of 235 East 42nd Street, New York, New York 10017, assignee of record.

RELATED APPEALS AND INTERFERENCES

There are no related appeals, or interferences which would have any affect or which would be affected by or have a bearing on any decision in the present appeal.

STATUS OF THE CLAIMS

Claims 1-13 are the subject of the present appeal and in the appendix herewith. Claim 1, amended on February 15, 2005 has been entered.

STATUS OF THE AMENDMENTS

The amendment to claim 1 submitted in the February 15, 2005 communication, which was made in response to the Final Action, has been entered. Consequently, claim 1 now includes the term "solution."

SUMMARY OF CLAIMED SUBJECT MATTER

The present invention, as claimed, encompasses an essentially non-aqueous, liquid concentrate solution composition for the oral administration of sertraline or a pharmaceutically acceptable salt thereof and one or more pharmaceutically acceptable excipients. In addition, the

present invention provides a method of using this concentrate composition to treat a variety of diseases.

GROUNDS FOR REJECTION TO BE REVIEWED ON APPEAL

Claims 1-13 stand rejected under 35 U.S.C 103(a)as being obvious over Doogan et al. (U.S. 4,962,128) in view of Howard et al. (U.S. 5,597,826).

ARGUMENT

The rejection:

In the Final Rejection, the Examiner rejected claims 1-13 as being unpatentable over Doogan et al. (U.S. 4,962,128) in view of Howard et al. (U.S. 5,597,826). Specially, the Examiner states that Dogan teaches a composition containing sertraline for treating anxiety, which includes oral formulations with diluents such as ethanol, propylene glycol, and glycerin; and that Howard teaches a composition containing sertraline including non-aqueous vehicles, such as ethyl alcohol, as well as oral formulations. The Examiner concludes that it would be obvious for a skilled artisan in the art to have combined these references and develop a product containing non-aqueous liquid concentrate solution compositions containing sertraline.

In response, Applicants submitted an amendment after Final Rejection which distinguished the instant claims over

the prior art, wherein the term "solution" was included in claim 1 such that the composition of claim 1 included "an essentially non-aqueous, liquid concentrate solution."

However, the Examiner maintained his Final Rejection, in light of the amendment, stating that the amendment was irrelevant. The Examiner based his decision, in part, by adopting the definition of "solution" as "a liquid preparation that contains one or more soluble chemical substances dissolved in water." Further, The Examiner states that because the specification points out that the phase "essentially non-aqueous" in claim 1 refers to the "about 10% water," that it becomes obvious that the Doogan's oral administration in the form of aqueous suspensions and/or elixirs does encompass the claimed solution.

Discussion:

Applicants respectfully submit that the Examiner's adopted definition of solution in his response to the amendment after the Final Rejection is too narrow and incorrect. The Examiner appears to take the definition of solution as substances dissolved only in water. However, the definition of "solution" includes mixtures dissolved in any solvent, wherein water is but one example. This definition is consistent with both the ordinary meaning of

the word and its meaning as used in the art. The American Heritage College Dictionary (3rd ed., page 1296) defines solution as "a homogeneous mixture of two or more substances, which may be solids, liquids, gases, or a combination of these." Further, Hawley's Condensed Chemical Dictionary (13th ed., page 1034) defines solution as "a uniformly dispersed mixture at the molecular or ionic level, of one or more substances (the solute) in one or more other substances (the solvent)." Hawley's further defines the term "solvent" (see page 1035) and gives several examples including hydrocarbons, aromatic hydrocarbons, esters, ethers, ketones, amines, and water.

Both of the above definitions illustrate that the Examiner's definition of the term "solution" which includes only water as the solvent is incorrect both in the art and in laymen's terms.

Further, applicants respectfully submit that the Examiner has taken the term "essentially non-aqueous," out of context, as defined in the specification (page 6, line 2). The Examiner states that the term refers to the amount of water present as being "about 10%." However, in the specification, the full sentence reads, "About 10% is the upper limit of the amount of water that may be present….Most typically, the amount of water that is

present ranges from about 0.8% to about 2.0% of the composition." Further, the instant specification explicitly points out that water is not directly added to the final product, but may merely be present in the active ingredient. Hence water is not directly or intentionally added (or even desired), but is an unintended and unavoidable consequence of production.

In view of the remarks above regarding the definitions of "solution" and "essentially non-aqueous," applicants respectfully submit that the Examiner's conclusions regarding the obviousness of the instant claims are also incorrect because they are based on incorrect presumptions by the Examiner regarding these definitions. As a result, applicants respectfully restate below the reasoning presented in applicants' amendment after Final Rejection, filed February 15, 2004.

The Examiner asserted in his Final Rejection, "...Doogan et al does teach the composition contains sertraline or its pharmaceutically acceptable salt, flavoring agents, and diluents, such as ethanol, glycerin and various like combinations thereof; also, the secondary Howard et al reference to supplement the primary reference does disclose that liquid preparations containing sertraline may be prepared by conventional means with pharmaceutically

acceptable additives such as non-aqueous vehicles (see col. 22, lines 47-55)."

Applicants respectfully submit that the above cited Doogan reference teaches diluents such as ethanol and glycerin within "...aqueous suspensions and/or elixirs ..." Applicants respectfully refer the Examiner to Dorland's Illustrated Medical Dictionary, 25th edition, (publ. W. B. Saunders) where on page 125 the definition of the term "aqueous" is given as "watery; prepared with water." Applicants further respectfully note that those skilled in the art will recognize that the term "aqueous" is used to describe a liquid preparation, wherein the liquid in the preparation is primarily water. Further it is clear to those skilled in the art that Doogan's recital at col. 2, line 63 of "When aqueous suspensions and/or elixirs are desired for oral administration ...." describes aqueous preparations. Therefore Doogan's recital of "...flavoring agents, coloring matter...", "emulsifying and/or suspending agents, together with diluents..." is within the context of diluents used with a liquid preparation wherein the liquid is primarily water and the resulting preparation is an emulsion or a suspension, not a solution as recited by instant claim 1.

The Examiner has invoked Howard, which teaches

pharmaceutical formulations with two active ingredients, as a secondary reference thus implicitly conceding that Doogan by itself neither teaches nor suggests the pharmaceutical composition of instant claim 1. The Examiner cites col. 22, lines 47-55 of the Howard reference which beginning at col. 22, line 47 and continuing to line 57, recites:

"Liquid preparations for oral administration may take the form of, for example, solutions, syrups or suspensions, or they may be presented as a dry product for constitution with water or other suitable vehicle before use. Such liquid preparations may be prepared by conventionalmeans with pharmaceutically acceptable additives such as suspending agents (e.g. sorbitol syrup, methyl cellulose or hydrogenated edible fats); emulsifying agents (e.g. lecithin or acacia); non-aqueous vehicles (e.g. almond oil, oily esters or ethyl alcohol); and preservatives (e.g. methyl or propyl p-hydroxybenzoates or sorbic acid)."

Applicants respectfully submit that the Examiner has relied on teachings in Howard that do not refer to pharmaceutical preparations in which the sole active ingredient is sertraline, or a pharmaceutically acceptable sertraline salt, but rather compositions containing (a) 5-HT reuptake inhibitors, of which sertraline is a preferred

species, and (b) an unspecified compound from the genus of compounds represented by Howard's formula I. The applicants respectfully refer the Examiner to the abstract, col. 1, line 6 - to col. 24, line 58 of the specification, and the claims, especially claim I at col. 64, lines 49 - 55). There is no suggestion in Howard that the compound of Howard's formula I is absent from or is to be removed from any preparation recited therein. Applicants submit the presence of another complex chemical species in Howard's pharmaceutical composition is a disincentive to the skilled artisan seeking guidance in the preparation of "an essentially nonaqueous, liquid concentrate solution ... comprising an amount of sertraline or a pharmaceutically acceptable salt thereof..." as it is unclear if Howard's teachings apply in the absence of compounds of Howard's formula I.

Applicants further submit that there is no indication in Howard that any of the means taught therein will produce "an essentially nonaqueous, liquid concentrate solution for oral administration comprising an amount of sertraline or a pharmaceutically acceptable salt thereof and one or more essentially nonaqueous pharmaceutically acceptable excipients" as recited in claim 1. In contrast, referring to the definition of the term "concentrate" in the

specification (see page 6, line 3) recites "'Concentrate' when used herein refers to a strong solution provided for dilution before use. (Butterworths Medical Dictionary, 2nd edition, Butterworths, London - Boston 1978, pp. 399-400.)"

Applicants further submit that Howard recites "... non-aqueous *vehicles (e.g.* almond oil, oily esters or ethyl alcohol)..." but the term vehicles, especially within the context of a formulation having two active ingredients, may refer to a medium in which these ingredients are suspended rather than dissolved. There is no recital in Howard that the "non-aqueous vehicles" specifically form a solution with sertraline alone or with pharmaceutically acceptable salts of sertraline alone as opposed to an emulsion or suspension, and there is certainly no recital of a concentrate solution, let alone the "nonaqueous liquid concentrate solution" of claim 1.

The Examiner further states "it is well-known in the art that many liquid preparations of conventional means with pharmaceutically acceptable additives are available depending on the customer's choice." Applicants respectfully submit that the Examiner errs if the Examiner is indicating that the availability of liquid pharmaceutical preparations in general, make obvious the invention of a specific liquid

pharmaceutical concentrate preparation designed to meet specific needs. Applicants respectfully submit that until a product based on the instant invention emerged no liquid concentrate solution of sertraline or a pharmaceutically acceptable salt thereof was available on the market. The Examiner concludes: "Therefore, if the skillful artisan ... had desired to develop the product containing non-aqueous liquid concentrate compositions of sertraline, it would have been obvious for the skillful artisan in the art to have [been] motivated to incorporate Howard et al's non-aqueous vehicles into the Doogan et al method because, for oral administration, Howard et al does indicate that non-aqueous vehicles can be incorporated in the liquid preparations containing sertraline."

Applicants further submit that Doogan's diluents and any combination thereof are in the context of *"aqueous* suspensions and/or elixirs." There is no recital in Doogan that specifically suggests that a "solution" let alone a "concentrate solution" and especially "an essentially nonaqueous, liquid concentrate solution" of sertraline or a pharmaceutically acceptable salt thereof can be achieved. The method of Doogan involves the use of water. The fact that Doogan teaches the use of water in all of the liquid preparations recited therein is in itself a disincentive to

the skilled artisan seeking "an essentially nonaqueous, liquid concentrate solution..." There is therefore no motivation for the skilled artisan to rely on the teachings of Doogan in the search for "an essentially nonaqueous liquid concentrate solution". Even if the step were taken of using Howard's non-aqueous vehicles in the absence of Howard's compounds of formula I the skilled artisan would expect that combining Howard's non-aqueous vehicles with Doogan's teachings would result in an aqueous emulsion or suspension not a concentrate solution. There is no teaching in either of the cited references either separately or combined in the manner suggested by the Examiner that suggests or hints at the pharmaceutical composition of claim I which is not merely a liquid preparation but an "essentially nonaqueous, liquid concentrate solution... comprising an amount of sertraline or a pharmaceutically acceptable salt thereof and one or more essentially nonaqueous pharmaceutically acceptable excipients..." Applicants respectfully submit, that there is no motivation, indeed there is a disincentive to combine Howard with Doogan.

The Examiner also stated in his Final Rejection that Doogan teaches "that it is administered in dosages ranging from 50 - 500 mg/day." Applicants submit that the stated dosage level gives noindication of the concentration of

sertraline or a pharmaceutically acceptable salt thereof attainable within any specific non-aqueous solvent system or what that solvent system should be. The aforesaid dosage refers only to oral or parenteral administration (see col 2, line 18) and "can be carried out in both single and multiple dosages" (see col. 2, lines 29 - 30) and may employ any one of the many dosage forms listed at col. 2, lines 35 - 37, such as tablets. Applicants submit "...an essentially nonaqueous, liquid concentrate solution ..." as recited in claim 1 is not among these dosage forms.

The Examiner also states that Doogan discloses at col. 2, lines 45 -46 that "the composition contains sertraline with concentration levels ranging from 0.5% to 90% by weight of the total compositions ... or its pharmaceutically acceptable salt, flavoring agents, and diluents such as ethanol, propylene glycol, and glycerin (see from col. 2 line 65 to col. 3, line 2)." Applicants submit that the composition referred to at col. 2, lines 45 -46 may be any one of the many dosage forms listed at col. 2, lines 35 - 37, such as tablets. Applicants submit there is no reference to any "essentially nonaqueous, liquid concentrate solution ...." or to the concentration of sertraline or a pharmaceutically acceptable salt thereof that can be dissolved to form such a concentrate solution. Applicants

submit that the diluents at col. 2 line 65 to col. 3, line 2 are directed to *"aqueous* suspensions and/or elixirs" (see col. 2, lines 63 - 64) and do not suggest or hint at the "essentially *non-aqueous* liquid concentrate solution" of claim 1.

The Examiner cites Howard as teaching "the dose of 0.3 mg to 10 mg per kg of body weight per day of the sertraline", at col. 23, lines 33 - 34. Applicants respectfully question the relevance of this teaching to the instant claims. Applicants submit that (a) any pharmaceutical preparation will be directed to delivering an effective dose of the medication contained therein, as this is the purpose of a pharmaceutical preparation, (b) the recital of dose levels for sertraline in Howard does not teach or suggest the quantities of sertraline or a pharmaceutically acceptable salt thereof that may be dissolved in an "essentially nonaqueous, liquid concentrate solution" as instantly claimed and (c) the dosage range cited by the Examiner is for a 5-HT reuptake inhibitor that is preferably sertraline *administered in combination* with "preferably ... 0.1 mg to about 3 mg. per kg. of body weight per day of a compound of formula I ..." (see col. 23, lines 25 - 40, especially lines 36 - 38): therefore this dose level may not apply when Howard's compound of formula I is absent as in the instant invention. The Examiner states

"...it would have been obvious for the skillful artisan ... to have [been] motivated to incorporate Howard et al's non-aqueous vehicles into the Doogan et al method, thereby ascertaining the claimed dose by routine experimentation."

Applicants submit that because Howard has tailored his teachings to a pharmaceutical preparation containing a 5-HT reuptake inhibitor, that may preferably be sertraline, plus another active ingredient selected from a genus of compounds represented by Howard's formula I, the skilled artisan would not be motivated to combine Howard with Doogan, indeed the constant presence of another active ingredient would be a disincentive to such a combination.

Applicants further respectfully submit that the Examiner has confused the term "dose" with the quantity of material dissolved in the concentrate solution of instant claim 1. At any given sertraline or sertraline salt concentration, the dose delivered will depend on the volume of solution delivered. Claim 1 recites "an essentially nonaqueous, liquid concentrate solution ... comprising an amount of sertraline or a pharmaceutically acceptable salt thereof" not doses. The instant invention provides a concentrated solution of sertraline or a pharmaceutically acceptable salt thereof so that an appropriate dose may be contained in a small volume of said solution, which as

recited in the specification, can be dispersed in a relatively large volume of a beverage. Applicants submit that disclosure of the dosages of sertraline that may be administered in any of many dosage forms such as tablets is not the disclosure of the solubility of sertraline or its salts in a non-aqueous solvent or a combination of non-aqueous solvents.

As discussed above, applicants submit that even if Howard were combined with Doogan in the manner suggested by the Examiner, the essentially nonaqueous concentrate solution of claim 1 would not be produced. Indeed the Examiner concedes in the statement "...thereby ascertaining the claimed dose by routine experimentation." that the mere combination of Howard with Doogan is not enough to produce the concentrate solution of claim 1 since further experimentation would be required. Applicants submit that claim 1 is therefore unobvious over the cited references under 35 USC 103(a). Applicants further submit that the Examiner's concession that "routine experimentation" would be required after combination of Howard with Doogan in the manner suggested by the Examiner, does not render the instant invention as recited in claim 1 unpatentable under 35 USC 103(a), which recites "Patentability shall not be negatived by the manner in

which the invention was made."

The Examiner also states: "However there is a motivation to combine the references. Doogan, et al. does disclose the pharmaceutical composition containing sertraline hydrochloride (see col. 1, line 68) with a dose from 25 mg to 200 mg for treating anxiety-related disorders (see col. 2, lines 20 -23);" Applicants submit that Doogan at col. 1, line 68, lists examples of "pharmaceutically acceptable salts of sertraline that can be used to treat anxiety-related disorders" but does not disclose a pharmaceutical composition. Applicants further submit that Doogan recites at col. 2, lines 16 - 21, "Sertraline or a pharmaceutically acceptable salt thereof, when used to treat anxiety-related disorders, may be administered either orally or parenterally. It is generally administered in dosages ranging from 50 - 500 mg per day when used to treat obsessive compulsive disorder, and from about 25-500 mg per day when used to treat other anxiety-related disorders," Applicants respectfully submit that the Examiner has confused the term dosage with the concentration of sertraline or a pharmaceutically acceptable salt in solution. The Examiner refers to Doogan col. 2, line 65 to col. 3, line 2 as listing diluents. The diluents listed also include water and the diluents refer to "aqueous

suspensions and/or elixirs" (col. 2, lines 63-64) but not an "essentially nonaqueous, liquid concentrate solution" as recited in claim 1. Applicants submit that the stated dosage range gives no indication of the concentration of sertraline or a pharmaceutically acceptable salt that is attainable within a specific non-aqueous solvent system or what that solvent system should be. The aforesaid dosage refers only to oral or parenteral administration (see col 2, line 18) and "can be carried out in both single and multiple dosages" (see col. 2, lines 29 - 30) and may employ any one of the many dosage forms listed at col. 2, lines 35 - 37, such as tablets. Applicants submit "...an essentially nonaqueous, liquid concentrate solution for oral administration..." as recited in claim 1 is not among these dosage forms.

The Examiner states "Howard et al. discloses expressly the pharmaceutical composition containing sertraline hydrochloride (see col. 20, line 31) with a dose of from 0.1 mg to 200 mg (see col. 24, lines 7-8), ... non-aqueous vehicles such as ethyl alcohol...." Applicants submit that while Howard at col. 20, line 31 refers to sertraline hydrochloride the reference to sertraline hydrochloride at Howard, col. 24, lines 7-8, is in error as the doses recited therein refer to the genus of compounds of formula I (see

col. 24, line 3). Applicants further submit that contrary to the Examiner's assertion, sertraline hydrochloride itself is never "expressly" disclosed in any of the pharmaceutical compositions described in Howard.

The Examiner asserts that Howard indicates at col. 20, lines 60-61 that pharmacologically acceptable anions for sertraline include methanesulfonate. Applicants respectfully submit that the Examiner errs. The aforesaid reference is to salts of the base compounds of Howard's formula I, not to sertraline.

Applicants further submit that Howard at col. 20, lines 63 - 66 refers to "Those compounds of the formula I which are also acidic in nature ... are capable of forming base salts with various pharmacologically acceptable cations." Applicants submit that such compounds of formula I due to the basic nature of sertraline or the cationic nature of a sertraline salt can interact with sertraline or a sertraline salt with the possible formation of insoluble residues. Applicants submit that Howard has tailored his teachings to a pharmaceutical preparation that always contains (a) a 5-HT reuptake inhibitor, preferably sertraline, or a salt thereof, and (b) another compound selected from the genus of compounds represented by Howard's formula I which can interact with sertraline or a

salt thereof. Applicants submit that the skilled artisan would not be motivated to combine Howard with Doogan, since the constant presence of another active ingredient that can cause complications and the lack of teachings specifically related to sertraline and pharmaceutically acceptable salts thereof would be a disincentive to such a combination.

The Examiner refers to col. 22, lines 51 -56, of Howard which discloses components that may be used in compositions containing the aforementioned two active components. Instant claim 1 recites a "an essentially nonaqueous, liquid concentrate solution ... comprising an amount of sertraline or a pharmaceutically acceptable salt thereof and one or more essentially nonaqueous pharmaceutically acceptable excipients; wherein at least one of the excipients is liquid.". Consequently, Howard's teaching of suspending agents is irrelevant and the teaching of non-aqueous "vehicles" such as ethyl alcohol does not disclose whether the vehicle produces a suspension, a solution or a combination of suspension and solution and does not teach or suggest a concentrate solution as recited in instant claim 1. There is no specific teaching in Howard of a composition whose only active ingredient is sertraline hydrochloride or any other pharmaceutically

acceptable sertraline salt. Applicants submit the Examiner's reference to Howard's teaching of methanesulfonate salt is not relevant as this refers to Howard's compounds of formula I and not to sertraline itself.

The Examiner appears to assert that both Doogan and Howard definitively deal with pharmaceutical compositions containing "sertraline hydrochloride". Applicants submit that contrary to this, Doogan does not specifically refer to sertraline hydrochloride in connection with any liquid preparation and Howard never specifically refers to sertraline hydrochloride in connection with any preparation. Furthermore, the Examiner confuses "dose" with the concentration of an ingredient in solution. Contrary to the assertion of the Examiner, neither reference specifically refers to sertraline hydrochloride in a liquid preparation, let alone a nonaqueous solution concentrate.

The Examiner describes the skillful artisan as being motivated to combine Howard's methanesulfonate "into the Doogan et al pharmaceutical composition containing sertraline hydrochloride ...." Applicants respectfully submit there is no motivation whatsoever for this combination as Howard refers to methanesulfonate only with regard to the genus of compounds of formula I, and

Doogan never specifically recites sertraline hydrochloride in any liquid preparation.

Applicants further submit that even if the references were to be combined in the manner described by the Examiner, the Examiner concedes that even after such combination the skilled artisan would need to perform "routine experimentations" "to achieve the non-aqueous liquid concentrate having the unique amounts and combination of excipients ...." Applicants respectfully submit that the Examiner has conceded that the amounts and combination of excipients of the non-aqueous liquid concentrate of instant claims 1-13 are "unique" and cannot be arrived at without further "routine experimentation". Applicants submit that the Examiner has conceded that the concentrate solution of instant claim 1 is therefore unobvious over the references combined in the manner suggested by the Examiner, as the amounts and composition are "unique" and must be arrived at by "routine experimentation". Applicants submit that 35 USC 103(a), recites "Patentability shall not be negatived by the manner in which the invention was made." Applicants request allowance of instant claim 1 and claims 2-13 since even if the manner by which the "unique" composition of instant claim I was achieved was "routine experimentation," it is patentable under 35 USC 103(a).

Applicants further respectfully submit that a non-aqueous sertraline hydrochloride concentrate solution based on the instant claims is currently being sold to meet the needs of patients who are non-compliant with treatment because they "...dislike or have difficulty swallowing tablets or capsules..." (see page 3 line 24 - page 4, line 2 of the instant specification). The applicants submit that the instant invention provides a technical solution to this problem in the form of the instant nonaqueous oral concentrate solution which permits the dispersal of the appropriate dose, contained in a very small volume of concentrate solution, in a large volume of a beverage having an acceptable taste. (See page 8, line 30 - page 9, line 7 of the instant specification.). Applicants submit that the commercial product based on the instant claims meets a long-felt need and that the instant claims are therefore patentable under 35 USC 103(a), and respectfully request withdrawal of the rejection and allowance of these claims.

For all of the foregoing reasons applicants submit that instant claim 1 is patentable under 35 USC 103(a) over the cited references, either separately or in the combination cited by the Examiner. Applicants further submit that claims 2-13 all of which incorporate the novel and

unobvious features of claim 1, are all patentable under 35 USC § 103(a) over the cited references, either separately or in the combination cited by the Examiner, and respectfully request withdrawal of the rejection.

Reversal of the Examiner and allowance of all the claims is accordingly respectfully requested.

Respectfully submitted,

Date: 8/2/05

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CLAIMS APPENDIX

1. (previously presented) A pharmaceutical composition which comprises: an essentially nonaqueous, liquid concentrate solution for oral administration comprising an amount of sertraline or a pharmaceutically acceptable salt thereof and one or more essentially nonaqueous pharmaceutically acceptable excipients; wherein at least one of the excipients is liquid.

2. (original) The composition of claim 1 wherein the pharmaceutically acceptable salt of sertraline is the hydrochloride salt or the mesylate salt.

3. (original) The composition of claim 1 wherein the excipients are selected from the group consisting of ethanol, glycerin, polyethylene glycol and propylene glycols.

4. (original) The composition of claim 3 wherein the excipients are ethanol and glycerin.

5. (original) The composition of claim 1 wherein the concentrate comprises sertraline hydrochloride in an amount of about 15 to about 30 mg/ml and wherein the excipients are ethanol and glycerin in an amount of about 8 to about 20% ethanol (by weight) in glycerin.

6. (original) The composition of claim 5 wherein the concentrate further comprises one or more flavoring agents and one or more pharmaceutically acceptable preservatives.

7. (original) The composition of claim 7 wherein the flavoring agents are selected from the group consisting of peppermint, spearmint and menthol; and wherein the preservatives are selected from the group consisting of butylhydroxytoluene, butylated hydroxyanisole, propyl gallate, ascorbic acid, ascorbyl palmitate, sodium metabisulfde, sodium bisulfate, sodium thiosulfate, sodium hydroxide, cysteine, ethylenediamine tetraacetic acid or salts thereof, citric acid, triethanolamine, thioglycerol, methylparaben and propylparaben.

8. (original)The composition of claim 7 wherein the flavoring agent is menthol and wherein the preservative is butylhydroxytoluene.

9. (original)The composition of claim 8 wherein each ml of the concentrate comprises about 22.4 mg of sertraline hydrochloride, about 151 mg of ethanol, about 0.50 mg of menthol, about 0.10 mg of butylhydroxytoluene, and about 1011 mg of glycerin.

10. (original) The compound, (1S-cis)-4-(3,4-didhlorophenyt)-1,2,3,4-tetrahydro-Nmethyl-1-naphthalenamine methanesulfonate.

11. (previously presented) A method of preparing an aqueous solution of sertraline comprising diluting an essentially nonaqueous, liquid concentrate of sertraline according to claim 1, or a pharmaceutically acceptable salt thereof, in an aqueous diluent prior to oral administration.

12. (previously presented) The method of claim 11, wherein the pharmaceutically acceptable salt of sertraline is the hydrochloride salt or the mesylate salt.

13. (previously presented) The method of claim 12 wherein the diluent is selected from the group consisting of water, orange juice, ginger ale, lemon-lime soda and lemonade.